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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,036	02/20/2002	Kathleen A. Elias	09367.0019.01000	9501

22852 7590 07/16/2004

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EXAMINER	
BRUSCA, JOHN S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,036	ELIAS, KATHLEEN A.	
	Examiner	Art Unit	
	John S. Brusca	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-34 and 36-45* is/are pending in the application.

4a) Of the above claim(s) *39-42,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-34,36-38 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 18 June 2004 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 24-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofland et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. The results are compared to a reference cell. In some embodiments, the effect of the agent is on extracellular matrix deposition, the two cells exhibit a diseased condition, and the two cells are grown in different compartments in the same medium.

Hofland et al. shows in figure 3 a visual assay of cells that were cocultured in a transwell apparatus. The cells were epithelial and fibroblast cells from human breast cancer tissue. The cells were treated with epidermal growth factor. The cells were immunostained for the presence

of keratin on the extracellular surface. Hofland et al. shows that epidermal growth factor and fibroblast cells enhance growth and keratin deposition in breast cancer epithelial cells. The results of Hofland et al. quantifies the amount of keratin. Hofland et al. shows in figure 3 staining of control cells with normal rabbit serum in panel b and of cocultured cells throughout.

4. Claims 24-29, 31-34, and 36-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stearns et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The results are compared to a reference cell. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. In some embodiments, the effect of the agent is on cell shape.

Stearns et al. shows coculture of human bone marrow endothelial cells and human epithelial prostate cancer cells. The cells are treated with IL-10 in Table 2 and with antibodies to MMP-2 and MMP-9 or antibodies to TIMP-1 in Table 1. Tables 1 and 2 show the results of the cell treatment on image determined length of microvessel formation (as depicted in figure 1). Stearns et al. show in the abstract and throughout that interleukin-10 and MMP-9/MMP-2 antibodies blocked formation of microvessels in the cultured cells. Reference cell comparisons are shown in tables 1 and 2.

5. Claims 24-34, 36-38, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Zietlow et al.

The claims are drawn to a method of predicting the effect of a drug on two different cocultured cells. The effect of the drug is determined by imaging the cells subsequent to exposure to the drug. The results are compared to a reference cell. In some embodiments, the

effect of the agent is on cell viability, the two cells exhibit a neurodegenerative diseased condition, in some embodiments the cells are neurons and glial cells, in some embodiments the two cells are grown in different compartments in the same medium.

Zietlow et al. shows in the abstract and figure 1 experiments in which microglial cells and neurons are cocultured in a two-well device that shares a common culture medium. The cells are treated with FMLP. Figure 2 shows the results of imaging the cells for tyrosine hydroxylase antigen by immunofluroescent microscopy as detailed in the methods section in the first column of page 1659. Figure 2 shows the results of viability of tyrosine hydroxylase cells after the coculture experiments. Figure 2 shows comparison of the results to control cells.

Response to Arguments

6. Applicant's arguments filed 11 May 2004 have been fully considered but they are not persuasive. The applicants point to the amendment from "quantitative phenotypic representation" to "phenotypic fingerprint" as distinguishing the claims from the prior art cited above. However the specification defines a fingerprint on page 28 as comprising scalar values or as a quantitative phenotype. Because the scope of the amended claims has not been altered the rejections are maintained.

Conclusion

7. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are

available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (571) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John S. Brusca 9 July 2004

John S. Brusca
Primary Examiner
Art Unit 1631

jsb